



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

Directorate General of Foreign Trade, Delhi / विदेश व्यापार महानिदेशालय, दिल्ली

VANIJYA BHAWAN, AKBAR ROAD, CENTRAL DELHI, DELHI, 110011 / वाणिज्य भवन, अकबर रोड, नई दिल्ली

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Feb/202324/24

DATED: 05/03/2024

Please Note

- I. For information of exporters, Norms Committee - III handles all cases pertaining to fixation/ratification of norms for Export Products falling under ITC (HS) Chapter 29, 30 .Communications in respect of cases/pertaining to NC- III may be sent to email address:
- II. The Norms Committee has taken decision only with respect to technical aspect/wastage norms. While redeeming the applications, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in Policy Circulars issued from time to time or any other provisions under FTP/HBP for EODC.
- III. Wherever the Committee has fixed Norms, the concerned RA may ensure that AA is issued on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less.

Meeting No. NC/3/MEET/Feb/202324/24 dated 05/03/2024 of Norms Committee - III for the year 2023-24 was held on 05/03/2024 under the Chairmanship of to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	UTTAM SARKAR,Assistant Section Officer	DGFT(HQ)
2	Raman Kumar,Deputy DGFT	DGFT(HQ)
3	NAND Lal,Technical Consultant	DPIIT
4	SHAISH KUMAR,Technical Consultant	DGFT
5	DINESHNARAIN MATHUR,Technical Consultant	DGFT
6	Nand Lal,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00007476AM24
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

Dr. Stavan Nagori Dy. GM (FD), Ms. Sonal Grewal, Dy. GM (PD), Shri Ketul Vakil, Dy. GM (Exim & Logistics) and Shri Devendra Mali, Manager of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MESALAMINE SUPPOSITORIES 1000 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MESALAMINE USP))	1 Number	1	MESALAMINE USP	1030.00 mg.
		2	HARDFAT NF	2060.300 mg.
		3	PRT100PVC30PE 58MM MESALAMINE SUPPOSITORIES 1000MG	200.00 mg.
		4	PRT100PVC30PE 60MM MESALAMINE SUPPOSITORIES 1000MG	205.00 mg.

Note: For export to USA only.

RA concerned may take further necessary action as per above decision of NC

Case No.	2 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024																			
HQ File Number	HQRNORM APPLY 00164102AM22																			
RA File Number	03AA04065031 AM22																			
Licence No and Date	0311006216/17/08/2021																			
Norms Committee Decision:																				
Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">Sacubitril /Valsartan((Net Contain of - 2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid - 300 Kgs, Net Contain of - L-Valine - 253 Kgs & Net Contain of - 4-Bromomethyl-2-Cyanobiphenyl - 470.00 Kgs))</td><td rowspan="3">500 kg</td><td>1</td><td>2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid</td><td>279.6 kg.</td></tr><tr><td>2</td><td>L-Valine</td><td>170.0 kg.</td></tr><tr><td>3</td><td>4-Bromomethyl-2-Cyanobiphenyl</td><td>220.0 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sacubitril /Valsartan((Net Contain of - 2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid - 300 Kgs, Net Contain of - L-Valine - 253 Kgs & Net Contain of - 4-Bromomethyl-2-Cyanobiphenyl - 470.00 Kgs))	500 kg	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid	279.6 kg.	2	L-Valine	170.0 kg.	3	4-Bromomethyl-2-Cyanobiphenyl	220.0 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
Sacubitril /Valsartan((Net Contain of - 2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid - 300 Kgs, Net Contain of - L-Valine - 253 Kgs & Net Contain of - 4-Bromomethyl-2-Cyanobiphenyl - 470.00 Kgs))	500 kg	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid	279.6 kg.																
		2	L-Valine	170.0 kg.																
		3	4-Bromomethyl-2-Cyanobiphenyl	220.0 kg.																
RA concerned may take further necessary action as per above decision of NC																				

Case No.	3 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00192148AM22
RA File Number	03AA04091496 AM22
Licence No and Date	0311007180/23/09/2021
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 01/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	4 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM REVIW00000165AM24

RA File Number	03AX04000308 AM22
Licence No and Date	0311009920/30/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 01/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	5 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00346268AM22
RA File Number	34AX04000204 AM22
Licence No and Date	3411001767/07/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 04/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	6 / NC/3/MEET/Feb/202324/24										
Case Status	Case Approved										
Party Name	INTAS PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024										
HQ File Number	HQRNORM REVIW00006124AM24										
RA File Number	08AX04000605 AM22										
Licence No and Date	0811004316/08/03/2022										
Norms Committee Decision:											
Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH</td><td>1 Number</td><td>1</td><td>DOXYCYCLINE MONOHYDRATE EP / BP / IP /</td><td>107.37 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP /	107.37 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP /	107.37 mg							

UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.)]			USP / PH. EUR. (Average water content NLT 4.30%)	
RA concerned may take further necessary action as per above decision of NC				

Case No.	7 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00380949AM22
RA File Number	34AX04000157 AM22
Licence No and Date	3411001935/09/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 04/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	8 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00000485AM23
RA File Number	03AX04000399 AM23
Licence No and Date	0311014263/29/04/2022
Norms Committee Decision: Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

RA concerned may take further necessary action as per above decision of NC

Case No.	9 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00001959AM23
RA File Number	03AX04002151 AM23
Licence No and Date	0311016241/11/07/2022
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 01/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	10 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00003003AM23
RA File Number	03AX04002647 AM23
Licence No and Date	0311017727/08/09/2022
Norms Committee Decision:	
Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -	

Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
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RA concerned may take further necessary action as per above decision of NC

Case No.	11 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00003129AM23
RA File Number	08AX04000980 AM23
Licence No and Date	0811006023/15/09/2022

Norms Committee Decision:

Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR. (Average water content NLT 4.30%)	107.37 mg

RA concerned may take further necessary action as per above decision of NC

Case No.	12 / NC/3/MEET/Feb/202324/24
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Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00003252AM23
RA File Number	03AX04002221 AM23
Licence No and Date	0311018044/21/09/2022
Norms Committee Decision:	
The firm vide letter their dated 05.03.2024 has informed that they have redeemed the license from concerned RA, therefore, the Committee after due deliberation decided to withdraw the application of the firm. A copy of redemption letter also given by the firm during Personal Hearing meeting.	

Case No.	13 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00003283AM23
RA File Number	03AX04003060 AM23
Licence No and Date	0311018071/22/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 01/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	14 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00003358AM23
RA File Number	03AX04002988 AM23
Licence No and Date	0311018145/25/09/2022
Norms Committee Decision:	
Shri Naresh Shah, Executive Director and Shri Rajesh Shingote, Director of the firm had attended the Personal Hearing,, in the meeting the firm informed that they are getting many intermediates manufactured by their supporting manufacturer, details of for which was not given. The firm also could not explain the confusion raise by committee in the yields claim in the process. Keeping the above issue in mind the firm stated that they would come with revised Application.	

Case No.	15 / NC/3/MEET/Feb/202324/24
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Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM REVIW00005140AM24
RA File Number	08AX04001050 AM23
Licence No and Date	0811006214/10/10/2022

Norms Committee Decision:

Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR. (Average water content NLT 4.30%)	107.37 mg

RA concerned may take further necessary action as per above decision of NC

Case No.	16 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00004528AM23
RA File Number	03AX04003867 AM23
Licence No and Date	0311019424/22/11/2022

Norms Committee Decision:

Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and

explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

RA concerned may take further necessary action as per above decision of NC

Case No.	17 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00004663AM23
RA File Number	03AX04004308 AM23
Licence No and Date	0311019588/29/11/2022

Norms Committee Decision:

Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

RA concerned may take further necessary action as per above decision of NC

Case No.	18 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00004807AM23
RA File Number	03AX04004440 AM23
Licence No and Date	0311019755/05/12/2022

Norms Committee Decision:

Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

RA concerned may take further necessary action as per above decision of NC

Case No.	19 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM REVIW00005141AM24
RA File Number	08AX04001419 AM23
Licence No and Date	0811006678/07/12/2022

Norms Committee Decision:

: Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR. (Average water content NLT 4.30%)	107.37 mg

RA concerned may take further necessary action as per above decision of NC

Case No.	20 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00005568AM23
RA File Number	34AX04000926 AM23
Licence No and Date	3411003231/05/01/2023
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed the firm could not attend the PH and requested vide e-mail dated 04/03/2024 to give one more opportunity to attend Personal Hearing. Therefore, the committee has decided to grant the permission for again Personal Hearing with relevant documents/information.	

Case No.	21 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00006058AM23
RA File Number	03AX04005325 AM23
Licence No and Date	0311021126/03/02/2023
Norms Committee Decision: Shri Somnath Dutta, Sr. GM and Ms. Rajni Sakpal, Head Exim of the firm had attended the Personal Hearing and	

explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

RA concerned may take further necessary action as per above decision of NC

Case No.	22 / NC/3/MEET/Feb/202324/24
Case Status	Case Rejected
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM REVIW00006482AM24
RA File Number	08AX04001877 AM23
Licence No and Date	0811007279/10/02/2023

Norms Committee Decision:

Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has observed that the firm could not furnish the proper justification for enhancement of wastage, Hence, it was decided to **reject** the case maintaining the **status quo**.

Case No.	23 / NC/3/MEET/Feb/202324/24
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM REVIW00006483AM24
RA File Number	08AX04002002 AM23
Licence No and Date	0811007388/27/02/2023

Norms Committee Decision:

Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the

firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PROPAFENONE HYDROCHLORIDE TABLETS 150 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG)	1 Tablet	1	PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (Potency on dried basis 99.1 %)	153.77 mg/Tablet
PROPAFENONE HYDROCHLORIDE TABLETS 300 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG [IN WHICH ACTIVE INGREDIENT ROPAFENONE HYDROCHLORIDE USED IS 283.500 KGS.])	1 Tablet	2	PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (Potency on dried basis 99.1 %)	306.675 mg/Tablet

RA concerned may take further necessary action as per above decision of NC

Case No.	24 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00006770AM23
RA File Number	03AX04005861 AM23
Licence No and Date	0311021934/06/03/2023

Norms Committee Decision:

Shri Naresh Shah, Executive Director and Shri Rajesh Shingote, Director of the firm had attended the Personal Hearing,, in the meeting the firm informed that they are getting many intermediates manufactured by their supporting manufacturer, details of for which was not given. The firm also could not explain the confusion raise by committee in the yields claim in the process. Keeping the above issue in mind the firm stated that they would come with revised Application.

Case No.	25 / NC/3/MEET/Feb/202324/24
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024
HQ File Number	HQRNORM APPLY 00000740AM24
RA File Number	03AX04000488 AM24
Licence No and Date	0311023468/10/05/2023
Norms Committee Decision: Shri Naresh Shah, Executive Director and Shri Rajesh Shingote, Director of the firm had attended the Personal Hearing,, in the meeting the firm informed that they are getting many intermediates manufactured by their supporting manufacturer, details of for which was not given. The firm also could not explain the confusion raise by committee in the yields claim in the process. Keeping the above issue in mind the firm stated that they would come with revised Application.	

Case No.	26 / NC/3/MEET/Feb/202324/24										
Case Status	Case Approved										
Party Name	INTAS PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 24 and 05/03/2024										
HQ File Number	HQRNORM REVIW00006125AM24										
RA File Number	08AX04000579 AM24										
Licence No and Date	0811008604/05/07/2023										
Norms Committee Decision:											
Dr. Manish Kumar Chauhan, Vice-President (FD) and Shri Hemang Vaishnav of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE</td><td>1 Number</td><td>1</td><td>DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR. (Average water content NLT 4.30%)</td><td>107.37 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR. (Average water content NLT 4.30%)	107.37 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR. (Average water content NLT 4.30%)	107.37 mg							

MONOHYDRATE USED IS 106.000 KGS.))				
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RA concerned may take further necessary action as per above decision of NC