

NMPA

Chemical API registration approval letter

Registration number: Y20210001017

Acceptance number: JYHS2260050

Approval letter number: 2024YS00951

Chemical API name	Generic Name: Ambroxol hydrochloride English name: Ambroxol hydrochloride		
Chemical API specification number	YBY71242024	Shelf-life	36 months
Package size	5kg/barrel, 10kg/barrel, 25kg/barrel		
Application item	Overseas production of chemical API for market application		
Approval Conclusion	See attachment		
API MAH	Chinese name: --- English name: Anuh Pharma Ltd. Address: E-17/3, E-17/4 & E-18, OPP. BRIJ ICE FACTORY, M.I.D.C, TARAPUR, BOISAR THANE 401506 MAHARASHTRA STATE, INDIA		
Manufacturing site	Chinese name: --- English name: Anuh Pharma Ltd. Address: E-17/3, E-17/4 & E-18, OPP. BRIJ ICE FACTORY, M.I.D.C, TARAPUR, BOISAR THANE 401506 MAHARASHTRA STATE, INDIA		
Packaging site	Chinese name: --- English name: --- Address: ---		
Approval letter expired date	To 2029-09-17		
Attachment	☒ Production process ☒ Specification ☒ Label ☐ Post approval commitment ☐ Others		
To	Shanghai Inspo Chemical Co.Ltd., (上海启点化工有限公司)		
CC	China NIFDC, National Pharmacopoeia Commission, NMPA CDE, NMPAIC, NMPA CFDI, Drug Registration Department of NMPA, Drug Supervision Department of NMPA		
Remark			

